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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,303	07/06/2001	Geert Maertens	2752-52	3515

23117 7590 04/07/2005

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 09/899,303	Applicant(s) MAERTENS ET AL.	
	Examiner Bao Qun Li	Art Unit 1648	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 27 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires one months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Office Action.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☒ Other: Interview summary.

Bao Qun Li

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**Advisory Action**

The response to the final action filed on August 27, and October 27, 2004 under 37 CFR 1.116 has been acknowledged. The request for reconsideration in combination with declaration has been fully considered. However, it is not found persuasive to overcome the rejection. Therefore, the amendments of claims and new claim 102 are not entered.

***Declaration***

The Declaration filed on 10/27/2004 under 37 CFR 1.132 has been acknowledged and considered. However, it is not insufficient to overcome the rejections.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 95, 96 and 97 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action because the entrees of amendments filed on August 27, 2004 and October 27, 2004 have been denied.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 77 and 98-101 are still rejected under 35 U.S.C. 112, first paragraph, because the specification on the same ground as stated in the previous Office Action due to the deny entrees of amendments filed on August 27, 2004 and October 27, 2004.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 76 is still rejected under 35 U.S.C. 102(e) as being anticipated by Watanabe et al. (US Patent No. 5,610,009A) on the same ground as stated in the previous Office Action.

3. In response to the previous Office Action, Applicants filed a declaration and submitted that the deleted region of 260-296 does not contain any glycosylation sites because the region of 260-296 does not contain any glycosylation sites. Therefore, the polypeptide disclosed by the prior art does not anticipate the claim.

4. Applicants' argument has been considered; however, it is not found persuasive because the claimed vector comprising HCV E1 protein starting from the region of amino acid residue 117 and 192 and ends in the region of amino acid residue 250 and 400. There are 5 glycosylation sites in E1 located at amino acid residues 196, 209, 234, 305 and 325. While the construct of pHCV419 does not contain the glycosylation site, the HCV construct pHCV422 disclosed by Watanabe et al. comprises the amino acid residues 117-279 of E1 expressed by pRc/CMV vector, which does not contain the fragment from amino acid residues 280 to 386 of E1. Therefore, the glycosylation sites at position of 305 and 325 are removed at the nucleic acid level (See Example, 1 and 2, especially, lines 35-41 on col. 13). Therefore, the reference of Watanabe et al. still anticipate claim 76.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 68-70, 73-74, 76, 79, 85-90 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Lanford et al. (Virology 1993, Vol. 197, pp. 225-235), Ralston et al. (J. Virol. 1993, Vol. 67, pp.6753-6761), Watanabe et al. (US Patent No. 5,610,009A) and Ford et al. (Protein expression and purification 1991, Vol. 2, pp. 95-107) under the same ground as stated in the previous Office Action.

7. Applicants traverse the rejection by arguing that the claimed invention is not taught and suggested by the combination of cited art.

8. Applicants' argument has been considered; however, it is not found persuasive because the combinations of the reference teach each and every imitation of claims. Applicants filed a declaration and submit that the deletion region of 260-296 does not contain any glycosylation sites because the region does not contain any glycosylation sites. Therefore, the polypeptide disclosed by the prior art does not anticipate the claim.

9. Applicants' argument has been considered; however, it is not found persuasive because the claimed vector comprising HCV E1 protein starting from the region of amino acid residue 117 and 192 and ends in the region of amino acid residue 250 and 400. There are 5 glycosylation sites in E1 located at amino acid residues 196, 209, 234, 305 and 325, the HCV construct pHCV422 disclosed by Watanabe et al. comprises the amino acid residues 117-279 of E1 expressed by pRc/CMV vector, which does not contain the fragment from amino acid residues 280 to 386 of E1. Therefore, the glycosylation sites at position of 305 and 325 are removed at the nucleic acid level (See Example, 1 and 2, especially, lines 35-41 on col. 13). Therefore, the reference of Watanabe et al. still anticipate claim 76.

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10. Since Lanford et al. teach a recombinant live eukaryotic vector for expressing an HCV E1 protein, Ralston et al. teach to use a vaccinia viral vector for expressing HCV E1 protein and Fort et al. teach a method for making a fusion protein with a tag, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references to use a vaccinia vector to express the E1 protein absence unexpected results. The rejection is therefore, maintained.

***Conclusion***

Claims 68-70, 73-74, 76-79, 85-91, 95-101 are pending.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

04/01/2005

  
JAMES HOUSEL 4/4/05  
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